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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,647	07/30/2003	Junya Yoneda	239534US0CONT	6857
22850	22850 7590 06/02/2006		EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			SOROUSH, LAYLA	
			ART UNIT	PAPER NUMBER
	·		1617	
			DATE MAILED: 06/02/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No. Application No. Applicant(s) YONEDA ET AL.			A	A				
### Examiner Layls Scroush 1617 - The MAILING DATE of this communication appears on the cover sheet with the correspondence address — Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Exeminions of time may be available under the provisions of 37 CPR 1.136(b). In or event, however, may a regly be intelly filed. If NO persod trong is specified shows, the maximum studies precision signal and ultrapies NE (MONTHS from the mailing date of this communication. February or plants to precise specified shows, the mailing date of this communication, even if shows it is supplicated in the scring dates of the communication, even if shows it is supplicated in the mailing date of this communication, even if shows it is supplicated in the communication of the mailing date of this communication, even if shows it is supplicated in its condition for allowance except for formal matters, prosecution as to the merrits is closed in accordance with the practice under Exparte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4 \(\text{Q}\) Claim(s) is/are pending in the application. 4 \(\text{Q}\) Claim(s) is/are allowed. 6 \(\text{C}\) Claim(s) is/are rejected. 7 \(\text{C}\) Claim(s) is/are rejected. 7 \(\text{C}\) Claim(s) is/are rejected. 9 \(\text{C}\) The drawing(s) filed on is/are: a) \(\text{ accepted or b}\) Objected to by the Examiner. Application Papers 9 \(\text{T}\) The paper filed oppies of the priority documents have been received. 2 \(\text{C}\) Certified copies of the priority documents have been received in Application No a) \(\text{L}\) Certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 2 \(\text{D}\) Notice of References Cited (Application No.	Applicant(s)				
Layla Soroush	Office Action Summary		10/629,647	YONEDA ET AL.				
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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-13, drawn to a composition comprising orinithine and/or one or more branched amino acids, classified in class 514, subclass 564.
- II. Claims 14-21, drawn to a method of treating or preventing an inflammatory disease, which comprises administering an effective amount of orinithine and/or one or more branched amino acids, classified in class 514, subclass 564.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process of treating or preventing an inflammatory disease can be practiced with a corticosteroid.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper. The searches in non-patent literature databases are extensive and do not overlap thus presenting a search burden to be searched together. In searching Group I, Examiner will be focusing on the patentability of the composition itself, and not the method of treating or preventing an inflammatory disease of Group II.

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Conversely, in searching Group II, Examiner will be focusing on the patentability of the method of treating or preventing an inflammatory disease's and not the composition itself. Thus, Groups I and II have been appropriately restricted on the basis of being independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

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commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1 .48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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A telephone call was made to Mr. Frederick D. Vastine on May 15, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SREENI PADMANABHAN SUPERVISORY PATENT EXAMINER